I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: July 25, 2011
Electronic Signature for Kari Lynn Barnes: /Kari Lynn Barnes/

Docket No.: 292-PDD-99-20-CON-[70P2]
(PATENT)
EFS-WEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Peter L. Harris et al.

Application No.: 10/603,952 Confirmation No.: 3111

Filed: June 25, 2003 Art Unit: 3738

For: VASCULAR PROSTHESIS Examiner: D. H. Willse

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under 37 C.F.R. § 41.41(a)(1), this Reply Brief is filed within two months of the Examiner's Answer dated May 23, 2011, and is in furtherance of the Appeal Brief, filed on May 16, 2011.

The brief contains items under the following headings pursuant to M.P.E.P § 1208:

I.	Status of Claims
VI.	Grounds of Rejection to be Reviewed on Appeal
VII.	Argument
VIII.	Conclusion
APPENDIX	

I. STATUS OF CLAIMS

The status of claims remains as identified in the Appeal Brief submitted May 16, 2011, which is as follows:

A. Total Number of Claims in Application

There are 21 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 12-13, 23-26, 28-32
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 1-11, 14-22, and 27
4. Claims allowed: none
5. Claims rejected: 1-11, 14-22, and 27

C. Claims On Appeal

The claims on appeal are claims 1-11, 14-22, and 27.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed are as follows:

A. Whether claims 1-5, 7-11, 14, 16, 18, 19, and 21 are anticipated under 35 U.S.C. § 102 over Ehrenfeld?

B. Whether claims 6, 15, 17, 20, and 22 are unpatentable under 35 U.S.C. § 103 over Ehrenfeld?

C. Whether claim 27 is unpatentable under 35 U.S.C. § 103 over Matterson?

D. Whether claims 1-5, 7, 14, 16, 18, 19, 21, and 27 are anticipated under 35 U.S.C. § 102 over Pintauro?

E. Whether claims 6, 15, 17, 20, and 22 are unpatentable under 35 U.S.C. § 103 over Pintauro?

III. ARGUMENT

For the sake of brevity, the arguments in this Reply Brief do not repeat the arguments presented in the Appeal Brief. Instead, this Reply Brief addresses specific assertions and issues raised by the Examiner's Answer. Thus, Appellant continues to rely on the Appeal Brief as filed on May 16, 2011.

A. Claims 1-5, 7-11, 14, 16, 18, 19, and 21 Rejected under 35 U.S.C. § 102 over Ehrenfeld

The Examiner has left unaddressed a number of contentions of the Appellant. The points actually raised by the Examiner are generally either irrelevant to the determination of anticipation or support Appellant's position as articulated in the Appeal Brief.

1. Claim 1, and claims 4-5, 14, depending therefrom

The Examiner's Answer does not address the primary contentions of Appellant. First, the Examiner does not further respond to the deficiency of Ehrenfeld to disclose a uniform surface. Second, with respect to the tapering, the passage relied on by the Examiner, of which Appellant assertedly has overlooked, does not support any disclosure of a taper. Similarly, with respect to the incorrect figures assertedly presented by Appellant, each of Ehrenfeld's figures, including the prior art, portray the same general shape with respect to the diameters of the graft (the changes being to

the stitches of the crotch region, and the perimeter edge of the flanged region). (*See,* Ehrenfeld, col. 3:29-36.) The Ehrenfeld prior art figures suffer from the same deficiencies as presented by Appellant with respect to FIGS. 4 and 5. Further, the Examiner's reference to a submission within the parent application is inapplicable to the present determination of whether Ehrenfeld shows or describes a taper. The Examiner asserts that a document filed in the parent application is particularly important to show how much the first diameter portion actually varies along the length of the tube. However, because the claims recite a smaller second diameter, the amount by which the taper actually varies along the tube length is irrelevant as Ehrenfeld does not show or describe any taper. Accordingly, Ehrenfeld does not anticipate the claim 1.

As presented in the Appeal Brief, Ehrenfeld fails to show or describe a generally uniform surface. Instead, Ehrenfeld shows and describes a crimped surface that is created from a smaller tube attached to a larger tube. The crimped surface necessarily presents a varied surface in direct contradiction to the Examiner's definition of uniform. Even assuming, *arguendo*, that the crimped surface constitutes a uniform surface, claim 1 recites the tubular portion including a generally uniform surface and a first diameter that tapers to a smaller second diameter. Thus, the generally uniform surface created by the crimps of Ehrenfeld would constitute one diameter. This crimped surface then does not taper to a smaller second diameter, as claimed. The Examiner does not address these contentions.

Instead, in response, the Examiner asserts that Ehrenfeld column 2, lines 17-20 support the assertion that Ehrenfeld anticipates the present claim, which was assertedly overlooked by Appellant. (Examiner's Reply, p. 6.) This passage describes the prior art flanges created by suturing two tubes onto a larger tube before cutting the desired end formation. Specifically, this passage recites: "The reinforcement is hard and tends to cause crotch 16 to curve towards back toward straight portion 22 and makes it difficult to suture." (Ehrenfeld, col. 2:17-20.) The curvature of the flange caused by the presence of sutures however does not show or describe the claimed taper of the tube section. Instead, as previously described, the prior art described by Ehrenfeld is created from two tubes sutured together and formed into a larger tube. Therefore, the single tube diameter necessarily expands into the larger tube portion that creates the flange. The

curvature of the flange caused by the presence of the sutures is inapplicable to the determination of the diameter of the tubular portion. Even with this curvature, there is no section of the Ehrenfeld graft or the described prior art that tapers to a smaller diameter.

With respect to Appellant's reliance on Ehrenfeld's FIGS. 4 and 5 instead of the asserted prior art FIGS. 1-3, the figures relied on do not vary with respect to the prior art FIGS. 1-3 for the aspects relied on, including the lack of a first diameter parallel to an axis of the tubular portion, or the transition from the tubular portion to the toe being initially outwardly convex before a final concave portion. This will be shown below with respect to the recitations of claim 2, to which these figures were actually presented. Accordingly, the substitution of FIGS. 1-3 for FIGS. 4-5 does not address the deficiency of Ehrenfeld to show or describe the features of claim 1, for which no figures were presented. The disclosure recited in the Appeal Brief to show the deficiency of Ehrenfeld with respect to the features of claim 1 came from the Ehrenfeld background describing the prior art, including Figures 1-3. Accordingly, Appellant's position with respect to claim 1 is not refuted by the substitution of these figures.

With respect to the "Miscellaneous Incoming Letter" dated October 5, 2001, the Examiner alleges a discrepancy between FIGS. 11 and 12 presented in the Appeal Brief. First, it is noted that the contents of the "Miscellaneous Incoming Letter" are the national stage filing documents, including the transmittal, preliminary amendment, specification, drawings, and declaration, attached hereto for reference. The only difference in FIGS. 11 and 12 from the original national stage filing documents (from PCT/GB98/01418) and those presented in the Appeal Brief is that the latter are prepared formal drawings of the former. There is no substantive difference. Indeed, the formal drawings, including FIGS. 11 and 12 reproduced in the Appeal Brief, were submitted with the original filing papers of the Instant Application on June 25, 2003, and were approved in the parent application, U.S. Patent Application No. 09/762,761, having been published in the issued patent, U.S. Patent No. 6,589,278. Therefore, Appellant respectfully submits that the Examiner's allegation of inaccuracy is without merit.

In any event, the reliance on the alleged original submission in the parent application is inapplicable to the present determination of anticipation. With respect to FIG. 12 presented in the Appeal Brief, it is presented to show the parallel first diameter of claim 2, rather than the taper to the second diameter. With respect to FIG. 11, the amount of the taper is not relevant to whether Ehrenfeld shows or describes *any* taper. The Examiner states that these original national stage filing papers are "particularly important with regard to the issue of how much Appellant's so-called 'first diameter portion' actually varies along the length of the tube." (Examiner's Answer p. 6.) However, the claims recite a second diameter less than a first diameter. Nothing in the claim requires a threshold amount for the taper. Ehrenfeld does not show or describe a second diameter less than a first diameter, or any taper since Ehrenfeld describes a smaller diameter tubular section expanding into a larger diameter tubular section.

In view of the above, the Examiner has not addressed the deficiencies of Ehrenfeld to show or describe a uniform surface that has a first diameter that tapers to a smaller second diameter as recited by claim 1. Accordingly, Appellant submits that the crimps formed in the Ehrenfeld graft cannot fairly be interpreted as a tubular portion including a generally uniform surface that tapers from a first diameter to a smaller second diameter.

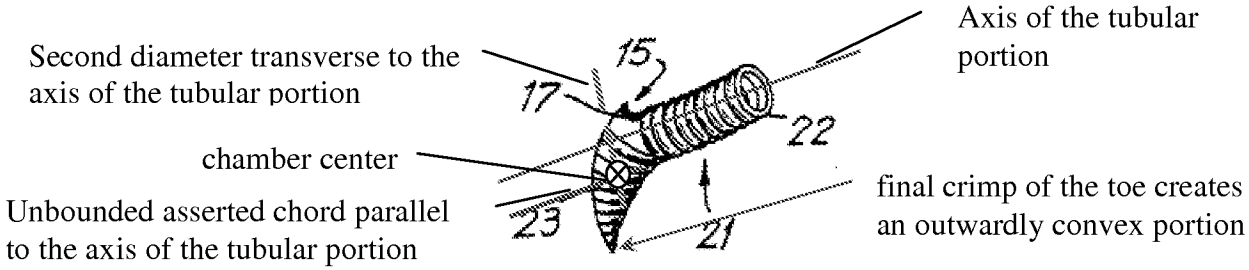
2. Claim 2

As stated above, the supposed misrepresentation of the Ehrenfeld FIG. 4 used in place of the prior art Ehrenfeld FIGS. 1-3 used by the Examiner is without effect as Ehrenfeld FIGS. 1-3 suffer from the same deficiencies. Specifically, no figure or disclosure of Ehrenfeld shows or describes a first diameter that is parallel to a longitudinal axis of the tubular portion, that is also longer than a second diameter transverse to the axis of the tubular portion, and that also corresponds to the toe and heel of the end formation. Accordingly, Ehrenfeld fails to anticipate claim 2.

As seen below in an annotated Ehrenfeld FIG. 2, a line passing through the center of the asserted chamber parallel to the axis of the tubular portion is unbounded on the cut end of the vascular graft. The examiner defines "diameter" as "a chord passing through the center of a figure

or body," and asserts that the boundary of the chord is the cut 18 of FIG. 1. (Examiner's Answer, p. 7.) However, an open cut end cannot form a boundary to the chamber as proposed. A chord is defined as "a straight line joining two points on a curve." ("Chord," Merriam-Webster on-line dictionary, http://www.merriam-webster.com/dictionary/chord?show=2&t=1311536095.) The cut of the Ehrenfeld prior art terminates any curve, such that there is no corresponding point along the curve that serves as the second point for the chord.

FIG. 2
PRIOR ART



Even assuming, *arguendo*, that a line taken through the center of the chamber, parallel to the tubular portion's axis, and terminating arbitrarily in space, may define the first diameter, Ehrenfeld does not show or describe the first diameter longer than a second diameter transverse to the axis of the tubular portion. Choosing an endpoint to a diameter terminating in open space renders this comparison difficult at best, if not entirely meaningless. However, as shown above, a transverse diameter appears substantially longer than any proposed first diameter parallel to the tubular portion. The relative size of any other transverse diameter (i.e. any going into or out of the page, across the chamber space) is insufficiently described or shown to make any comparison and therefore cannot anticipate the recited relative size of the first diameter to the second diameter.

Moreover, the asserted first diameter does not correspond to a heel and a toe of the end formation, as claimed. The Examiner does not provide a definition of "corresponds" that supports a finding that the arbitrary location of the asserted first diameter corresponds to the asserted heel and toe of the end formation. Instead, the Examiner asserts that since the first diameter *generally*

extends from a heel region to a toe region, this diameter corresponds to these areas. (Examiner's Answer, p. 7.) However, "correspond" is generally defined as "to be equivalent" or "to compare closely : match." ("Correspond," Merriam-Webster on-line dictionary, http://www.merriam-webster.com/dictionary/correspond.) Even assuming the asserted first diameter extends at all toward or away from the heel and toe regions, as shown above, the first diameter is nowhere near the actual toe and heal to be considered equivalent to, or to match with these areas. As such, any first diameter arbitrarily drawn in the open space of the chamber, that is also parallel to the axis of the tubular section, does not correspond to a toe and a heel of the end formation.

Appellant agrees that claim 2 does not necessarily require the diameters to extend across the *opening* of the chamber. However, a diameter of the chamber must be enclosed by the chamber. Further, as clearly recited by the claim, a first diameter must be parallel to the axis of the tubular portion, must be longer than a second diameter, and must correspond to the toe and heel of the end formation. These requirements are not simultaneously shown or described by the disclosure of Ehrenfeld, such that any one asserted first diameter of Ehrenfeld cannot anticipate the present claim 2.

Appellant also notes that the Examiner has not addressed how Ehrenfeld FIGS. 1-3 anticipate the claimed transition to a final concave portion at the toe. As shown above, Ehrenfeld FIG. 2 shows and describes the same configuration of Ehrenfeld FIG. 5 in which the crimp creates a final outwardly convex portion. No other features of Ehrenfeld FIG. 2 can be conceived to anticipate the initial convex to a final concave transition from the tubular portion to the toe, except by use of the crimps. The general shape of the curved toe section does not create a final concave portion. This edge section is not a transition from the tubular portion to the toe, nor is it outwardly concave, as claimed. Accordingly, Ehrenfeld additionally fails to anticipate claim 2 for failing to show or describe the claimed transition.

3. Claim 3

In response to Appellant's direct comparison of Ehrenfeld to the prior art described as specifically not providing the claimed configuration, the Examiner merely states that any fluid flow through a lumen inerhently is accompanied by shear stress. (Examiner's Answer, p. 7.) Even assuming *arguendo* that any fluid flow through a lumen is inherently accompanied by shear stress at the luminal walls, the claim does not recite this feature alone, but instead recites an enlarged chamber configured to *promote* localized movement having this relationship. Accordingly, any fluid flow that is inherently accompanied by some shear stress at the luminal walls does not necessarily promote the localized movement of blood having a non-laminar nature with a shear stress inducing relationship. Accordingly, Ehrenfeld does not anticipate the recitations of claim 3.

Appellant's definition does not alter this finding. Instead, as shown before, the configuration of Ehrenfeld is that of the prior art specifically disclosed by the present application to lack such a configuration. The definition identified by the Examiner recited in the parent application 09/762,761 states that the "term 'non-laminar' as used herein is intended to define blood flow other than parallel to arterial walls and, in particular, includes localized laminar movement of blood having significant secondary components." This understanding is consistent with the present disclosure that describes:

> The vascular prosthesis of the invention is intended to promote vertical blood flow in the region of its arterial connection in order to reduce or eliminate regions of low shear stress and regions of long residence times where blood elements can accumulate in the region of the graft connection. Separation of flowing blood from the inner all of the tube near its enlarged chamber, and associated with non-laminar flow, is preferably such as to produce a swirling action that may include locally circulatory or re-circulatory movement of blood, further preferably in the nature of or including a vortex action.

(Specification, p. 3, ¶ [0011].) This paragraph is the exact paragraph following the definition of non-laminar in the parent application.

4. Claims 7 and 16

Appellant reiterates the arguments of the Appeal Brief that claims 7 and 16 are patentable over Ehrenfeld. *See*, Appeal Brief § VII.A.4.

5. Claims 8 and 9, 10

Appellant reiterates the arguments of the Appeal Brief that claims 8, 9, and 10 are patentable over Ehrenfeld. *See*, Appeal Brief § VII.A.5.

6. Claim 11

Appellant reiterates the arguments of the Appeal Brief that claim 11 is patentable over Ehrenfeld. *See*, Appeal Brief § VII.A.6.

7. Claim 18, and claim 19, depending therefrom

The Examiner responds to the arguments of Appellant with respect to claim 18 by asserting that "extending along a majority of the length of the tube" modifies the immediately preceding term *portion* rather than the diameter of the "first diameter portion." (Examiner's Reply, p. 8.) However, the Examiner fails to present how this distinction permits Ehrenfeld to anticipate the claimed "first diameter portion" where that portion extends along a majority of the length of the tube. The portion claimed to extend along a majority of the length of the tube is still of a first diameter.

Also, the Examiner asserts that the instant claims should be read in light of the original drawings and specification instead of the allegedly misleading diagram in the Appeal Brief at the top of page 16. Appellant is unsure how a figure and description of the present specification can be misleading to the claims of that application. As noted above, FIG. 11 reproduced in the Appeal Brief is the substantively identical to FIG. 11 submitted with the original filing papers of the parent

application, U.S. Patent Application No. 09/762,761. The specification of the parent application describes FIG. 11 as similar to other embodiments described, but including a narrower portion prior to commencement of the enlargement to increase the velocity of blood flow through the graft connection to an artery. (U.S. Patent Application No. 09/762,761, Specification, p. 8, ll. 8-12.) Appellant is unaware of any position taken contradictory or misleading with respect to the position taken in the Appeal Brief, found either in the present application or the parent application.

8. Claim 21

The Examiner apparently responded to claim 21, along with claim 18, by asserting that "extending along a majority of the length of the tube" extends "portion" rather than "first diameter portion." Appellant has responded to this position above, with respect to claim 18. Appellant incorporates that position here with respect to claim 21 and further relies on the arguments as presented in the Appeal Brief to show that Ehrenfeld fails to show or describe a first diameter portion as claimed. Specifically, any reading of the claimed first diameter portion extending along a majority of the length of the tube that permits multiple diameters or along a length less than the majority of the length of the tube renders the claim language meaningless. A reading that the portion of the tube that extends along the length of the tube that is also not of a first diameter is unsupported, since the claim recites a "first diameter portion." Accordingly, Ehrenfeld fails to anticipate claim 21 of the present application.

B. Claims 6, 15, 17, 20, and 22 Rejected under 35 U.S.C. § 103 over Ehrenfeld

1. Claim 6

The Examiner does not specifically address further the contentions of Appellant with respect to claim 6. Accordingly, Appellant reiterates the arguments of the Appeal Brief that claim 6 is patentable over Ehrenfeld. See, Appeal Brief, § VII.B.1.

2. Claims 15, 17, 20, and 22

The Examiner does not specifically address further the contentions of Appellant with respect to claims 15, 17, 20, and 22. Accordingly, Appellant reiterates the arguments of the Appeal Brief that these claims are patentable over Ehrenfeld. See, Appeal Brief, § VII.B.2.

C. Claim 27 Rejected under 35 U.S.C. 103 over Matterson

An allegation that numerous materials and reinforced materials not requiring pleats or corrugations are (and were) used in the art, does not support the Examiner's position that the disclosure of Matterson would be altered by a person of skill in the art to remove the disclosed pleats. As previously noted, Matterson specifically describes the benefit of the pleats to maintain the graft in an open position even when bent, as well as providing a variable axial length through the accordion like expansion and contraction of the pleats. (Matterson, col. 6:46-54, 3:29-33.) The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. (MPEP § 2145, III, citing *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).) A "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (MPEP § 2141.02.) Nothing in Matterson or the level of skill in the art as presented by the Examiner would suggest going against the teaching of Matterson to remove the described pleats and frustrating the benefits of maintaining the graft in an open position while permitting the variable length.

Specifically, the Examiner asserts that numerous materials and reinforced materials do not require pleats. (Examiner's Answer, p. 8.) However, Matterson is specifically directed toward a woven graft with a cross-weave pattern to prevent unraveling. Changing the materials by the undisclosed references definitely frustrates the purpose of Matterson. Therefore, the undisclosed references to numerous materials and reinforced materials not requiring pleats or corrugations are irrelevant to the obviousness of the present claim in view of Matterson.

D. Claims 1-5, 7, 14, 16, 18, 19, 21, and 27 Rejected under 35 U.S.C. § 102 over Pintauro

1. Claim 1, and claims 4, 5, 14, and 16 depending therefrom

Whether Pintauro may be attached to a vessel through other means besides sutures is not at issue. Pintauro is not capable of acting as the claimed vascular prosthesis through any attachment method. Instead of the rubber preventing suturing to a blood vessel, it is the material and shape of Pintauro that prevents any attachment, through adhesive or otherwise, to a blood vessel. The Pintauro device is configured to fit within a bladder to maintain its position by the outward force of the anchor against the bladder through the use of reinforcing rings and spring wires. (*See*, Pintauro, col. 4:21-26.) Such outward force presented on a blood vessel would cause severe trauma to the vessel, thus rendering the Pintauro device incapable of use as a vascular prosthesis.

With respect to Pintauro preventing the flow of blood by the addition of the valve within the fluid flow path, the general reference to venous valves to assist the flow of blood upwardly along the legs of a human does not render the present claims anticipated by Pintauro. (Examiner's Answer, p. 9.) The disclosure of these venous valves is not identified, and therefore Appellant cannot reasonably respond to this position. In general, however, Pintauro does not appear capable of assisting in the one way flow of blood upward along the legs, such that any teaching in this regard would be applicable. It is conceivable that such a valve may be used to permit blood flow in one direction (i.e. upward along the leg), while preventing the back flow caused by gravity down the leg. However, Pintauro is a one way valve that *resists* passage of fluid in the direction of flow for low pressure differentials. (Pintauro, col. 5:15-20.) Such a configuration permits the bladder to retain urine until full, when the fluid may be release at one time, given the pressure build up. Such a configuration is inapplicable to the above proposed venous valves to assist in blood flow upwardly along the legs. It would appear that if a person requires such assistance, the blood flow pressure is minimal to overcome the resistance to an upward flow; otherwise, why would such devices be necessary? As such, adding a valve that would impede the passage of blood in the flow direction until a minimum pressure was obtained would further reduce the ability of the blood to proceed in the upward direction along the leg. Accordingly, the Examiner's reference to these venous valves

appears inapplicable to the present rejection that Pintauro anticipates the present claimed vascular prosthesis by preventing fluid flow.

The Examiner does not address with further specificity the deficiency of Pintauro to describes a first diameter portion tapering to a smaller second diameter portion adjacent the end formation. Accordingly, Appellant relies on the arguments presented in the Appeal Brief with respect to this deficiency.

2. Claim 2

The Examiner does not specifically address further the contentions of Appellant with respect to claim 2. Accordingly, Appellant reiterates the position taken in the Appeal Brief that Pintauro fails to disclose the claimed enlarged chamber including the first diameter and second diameter. *See*, Appeal Breif, § VII.D.2. To the extent applicable, Appellant also relies on the arguments presented above, section III.A.2, in response to the Examiner's position with respect to claim 2 as not anticipated by Ehrenfeld.

3. Claim 3

The Examiner does not specifically address further the contentions of Appellant with respect to claim 2. Accordingly, Appellant reiterates the position taken in the Appeal Brief that Pintauro fails to disclose the claimed configuration to promote localized movement. *See*, Appeal Brief, § VII.D.3. To the extent applicable, Appellant also relies on the arguments presented above, section III.A.3, in response to the Examiner's position with respect to claim 3 as not anticipated by Ehrenfeld.

4. Claims 7 and 16

The Examiner does not specifically address further the contentions of Appellant with respect to claims 7 and 16. Accordingly, Appellant reiterates the arguments of the Appeal Brief that these claims are patentable over Pintauro. *See*, Appeal Brief, § VII.D.4.

5. Claim 18

In view of the arguments in the Appeal Brief, see §VII.D.5, and the response present above, section III.D.1, Pintauro is not capable of being used as a vascular prosthesis as claimed. Accordingly, the Pintauro does not anticipate the recitations of claim 18.

6. Claim 19

The Examiner does not specifically address further the contentions of Appellant with respect to claim 19. Accordingly, Appellant reiterates the arguments of the Appeal Brief that claim 19 is patentable over Pintauro. *See*, Appeal Brief, § VII.D.6.

7. Claim 21

In view of the arguments in the Appeal Brief and the response present above, sections D.1, Pintauro is not capable of being used as a vascular prosthesis as claimed. Accordingly, the Pintauro does not anticipate the recitations of claim 21.

8. Claim 27

In view of the arguments in the Appeal Brief and the response present above, sections D.1, Pintauro is not capable of being used as a vascular prosthesis as claimed. Accordingly, the Pintauro does not anticipate the recitations of claim 21.

E. Claims 6, 15, 17, 20, and 22 Rejected under 35 U.S.C. 103 over Pintauro

1. Claim 6

The Examiner does not specifically address further the contentions of Appellant with respect to claim 6. Accordingly, Appellant reiterates the arguments of the Appeal Brief that claim 6 is patentable over Pintauro. *See*, Appeal Brief, § VII.E.1.

2. Claims 15, 17, 20, and 22

The Examiner does not specifically address further the contentions of Appellant with respect to claims 15, 17, 20, and 22. Accordingly, Appellant reiterates the arguments of the Appeal Brief that these claims are patentable over Pintauro. *See*, Appeal Brief, § VII.E.2.

IV. CONCLUSION

Further to the discussion above and Appellant's discussion in its Appeal Brief, Appellant submits that claims 1-11, 14-22, and 27 are patentable over the cited references. Therefore, Appellant respectfully requests that the Board overturn the rejections of pending claims 1-11, 14-22, and 27.

Appellant believes not fee is due with this response. In the event the U.S. Patent and Trademark Office determines that any fee and/or other relief is required, Appellant petitions for any required relief and authorizes the Commissioner to charge the cost of any fees due in connection with the filing of this document to Deposit Account No. **50-2191** referencing docket no. 101675.0070P2.

Dated: July 25, 2011

Respectfully submitted,

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APPENDIX

US Application Number 09/762,761 transmittal of national stage filing documents, including the transmittal, preliminary amendment, specification, drawings, and declaration; identified as "Miscellaneous Incoming Letter" filed October 5, 2001 in the electronic file.

02-12-01 JC08 Rec'd PCT/PTO 09 FEB 2001 CT 5

FORM PTO-1390
(Rev 10-9-94)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office
Docket No. 297912001620

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. § 371

09/762761

U.S. APPLICATION NO. (If known, see 37 C.F.R. § 1.5):

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB98/01418	May 15, 1998	May 17, 1997

TITLE OF INVENTION: VASCULAR PROSTHESIS

APPLICANT(S) FOR DO/EO/US: HARRIS, Peter, Lyon and HOW, Thien, Voon

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. § 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. § 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. § 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. § 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. § 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. § 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. § 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. § 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. §§ 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: Article 34 Amendment submitted May 12, 1999; return receipt postcard.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: ET157245272US Date of Deposit: February 9, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Fred Crooks

oc-162413

U.S. APPLICATION NO. (If known, see 37 C.F.R. § 1.5) * 09/762761	INTERNATIONAL APPLICATION NO. PCT/GB98/01418	DOCKET NUMBER: 297912001620

17.* ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 C.F.R. §§ 1.492(a)(1)-(5)):

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.....$840.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO.....$670.00

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International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provision of PCT Article 33(1)-(4).....$970.00

International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4).....$96.00

CALCULATIONS PTO USE ONLY		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$670.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(e)).	$*	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	* - 20 =	*	x $18.00	$*	
Independent claims	* - 3 =	*	x $78.00	$*	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$*	
			TOTAL OF ABOVE CALCULATIONS =	$*	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 C.F.R. §§ 1.9, 1.27, 1.28)				$*	
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Fee for recording the enclosed assignment (37 C.F.R. § 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§ 3.28, 3.31). **$40.00 per property**			+	$ 40.00	
			TOTAL FEES ENCLOSED =	$710.00	
				Amount to be refunded:	**$***
				charged:	**$***

a. ☒ A check in the amount of $710.00 to cover the above fees is enclosed.

b. ☐ Please charge my **Deposit Account No. 03-1952** in the amount of $* to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Assistant Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to **Deposit Account No. 03-1952**.

NOTE: Where an appropriate time limit under 37 C.F.R. § 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. § 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Todd W. Wight
Morrison & Foerster LLP
555 West Fifth Street
Suite 3500
Los Angeles, California 90013-1024

SIGNATURE

Todd W. Wight
Registration No. (45,218)

PATENT
Docket No. 297912001620
Client Reference 292-PDD-99-19 CIP

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: ET157245326US Date of Deposit: February 9, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Fred Crooks

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Harris, et al.

PCT Application Serial No.: PCT/GB98/01418

For: VASCULAR PROSTHESIS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This preliminary amendment is filed concurrently with the U.S. National Transmittal of the PCT application listed above. Applicants respectfully submit that the claims are in condition for allowance.

IN THE SPECIFICATION

On page 1, before line 1, please insert the following paragraph, --This application is related to U.S. Application Serial No. 09/183,132, filed October 30, 1998, which is a continuation of U.S. Application Serial No. 08/656,065, filed May 31, 1996, now U.S. Patent No. 5,861,026, and claims the benefit of United Kingdom patent application GB 9709967.5, filed May 17, 1997, which applications are incorporated by reference.--

CLAIMS

We Claim:

1. An implantable drug port, comprising a low profile housing, including a port top and a port base, wherein the port base further comprises a port stem, and a septum disposed within the housing, wherein a lumen is defined within the housing beneath the septum and accessible through the septum ***characterized in that*** at least two indicators are disposed on the housing, spaced apart along an axis of the housing.

2. The implantable drug port according to claim 1, wherein the indicators are formed from radiopaque material.

3. The implantable drug port according to claim 2, wherein the radiopaque material further comprises radiopaque paint.

4. The implantable drug port according to claim 1, wherein the indicators comprise a plurality of rings.

5. The implantable drug port according to claim 4, wherein the plurality of rings further comprises a lower ring of a first diameter disposed near a bottom of the drug port and an upper ring of a second diameter, different from the first diameter, disposed near a top of the drug port.

6. The implantable drug port according to claim 5, wherein the lower ring is interrupted creating a discontinuity.

7. The implantable drug port according to claim 4, wherein the plurality of rings are comprised of a metal selected from the group consisting of stainless steel, gold, platinum, tungsten tantalum and titanium.

8. The implantable drug port according to claim 4, wherein the plurality of rings are comprised of a resin and a powdered material selected from the group consisting of stainless steel, gold, platinum, tungsten tantalum, titanium and a barium compound.

9. The implantable drug port according to claim 1, wherein the indicators are formed to be distinguishable from each other by imaging when said drug port is implanted.

10. The implantable drug port according to claim 1, wherein the indicators comprise a lower locator ring and an upper locator ring, wherein the lower locator ring is interrupted creating a discontinuity, and is disposed at a bottom of the low profile housing such that the discontinuity is aligned with the port stem, and wherein the upper locator ring is placed between the septum and the port top.

11. The implantable drug port according to claim 10, wherein the low profile housing is encapsulated with a silicone rubber material.

12. The implantable drug port according to claim 2, wherein the radiopaque material further comprises radiopaque plastic material, wherein a lower ring is applied to a bottom portion of the port top and an upper ring is applied to an upper portion of the port top.

13. The implantable drug port according to claim 12, wherein the low profile housing is encapsulated in a silicone rubber material.

14. The implantable drug port according to claim 12, wherein the lower ring has a discontinuity such that the discontinuity is aligned with the port stem.

15. The implantable drug port according to claim 1, further comprising a radiopaque catheter connected to the port stem.

16. (Thrice Amended) A method for determining an orientation of an implantable drug port to assist in guiding a needle into the port, wherein the implantable drug port comprises a non-inflatable housing having a first and second side, a septum disposed within the housing and a first and second indicator spaced apart along a first axis of the housing, ***characterized by*** the steps of:

locating the implanted non-inflatable housing;

imaging the housing along a second axis not parallel to the first axis; and

determining the orientation of the housing with respect to the first and second sides.

17. The method according to claim 16, wherein the indicators comprise radiopaque material.

18. The method according to claim 17, wherein the radiopaque material is selected from the group consisting of gold, platinum, tungsten, tantalum, stainless steel, titanium and barium compounds.

19. The method according to claim 16, wherein at least one of the indicators is ring shaped.

20. The method according to claim 19, wherein the ring shaped indicator is interrupted creating a discontinuity.

21. The method according to claim 19, wherein a radiopaque catheter is disposed to bisect the ring shaped indicator.

22. The method according to claim 17, wherein the radiopaque material further comprises radiopaque plastic material.

23. A method for guiding a needle into an implantable drug port, including the step of implanting the drug port with the first axis normal to a patient's skin surface ***characterized by***:

providing a drug port comprising a non-inflatable housing, a septum disposed within the housing and a first and second indicator spaced apart along a first axis of the housing, wherein the indicators are distinguishable, one from the other, by an imaging technique;

employing the imaging technique to image the drug port along a second axis not parallel to the first axis;

determining the orientation of the drug port based on an imaged spatial relationship of the first indicator to the second indicator; and

inserting the needle into the septum at a location where the septum is accessible.

24. A medical device for implantation beneath a patient's skin surface designed to facilitate determination of device orientation by an imaging technique, comprising a first indicator and a second indicator disposed on the device and spaced apart along an axis normal to the skin surface when the device is implanted beneath the skin surface, ***characterized in that*** the second indicator is distinctly shaped from the first indicator.

REMARKS

This amendment is submitted with a national stage application of PCT Application Serial No. PCT/GB98/01418. The amendments to claims 1-6 are intended to place the claims in a form more conducive for examination. The added claims (7-12) describe further embodiments of Applicants invention (see p. 7, second paragraph and p. 8, first paragraph (Fig. 8) for support). Applicants submit that no new matter has been added and that the amendments herein are not made for reasons pertaining to patentability. Applicants respectfully submit that the pending claims are in condition for allowance and request an early notification of the same. In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 297912001620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: February 9, 2001 By: _____

Todd W. Wight
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TITLE: Prosthetic grafts

DESCRIPTION

This invention concerns prosthetic grafts for use in vascular surgery, particularly for by-passes to relatively small arteries.

By-passes required to save limbs can be long, say going from groins to below knees, and to arteries that may be as small as 1 to 5mm in diameter. Where patients have no other veins that can be used, as is often the case with patients having relevant serious conditions, the only positive alternative is to use prosthetic grafts of synthetic materials, for example flexible tubes of polytetrafluoroethylene (PTFE). Simple direct end connections or anastomosis of prosthetic graft tubes (usually run at an acute angle or more or less parallel with the artery and end cut at an angle) to side apertures in arteries, perhaps particularly arteries substantially less than 5mm in diameter, has unfortunately been followed by formation of fibrous intimal hyperplasia, which leads to serious blood flow reduction and even stoppage. The fibrous intimal hyperplasia occurs in regions within and around the graft connection, where there is little or no shear stress between the blood flow and the graft and arterial walls.

It is known to use a small piece of natural vein to make a short cuff known as the Miller cuff, that is joined by surgical stitching to and between the artery opening and the end of the prosthetic graft tube. Improved success rates for indirect prosthesis-to-vein-to-artery connection, compared with direct prosthesis-to-artery,

have involved reduced adverse effect from intimal hyperplasia. Contributory factors, for cuff type and other prosthesis types, have been considered and postulated as including reducing tendencies to turbulence of blood flow, and/or optimising approximation to laminar blood flow, and/or for suppleness of the natural vein parts to aid absorption or cushioning blood pulsing. These factors have further been seen particularly as contributing to avoiding or minimising occurrence of artery wall shear stress. However, fibrous intimal hyperplasia still occurs with the so called Miller cuff because regions of flow separation and low shear stress still occur within the cuff.

US – A-5156619 discloses a vascular prosthesis comprising a tube of material other than autologous vascular tissue, the tube having an enlarged end formation for surgical connection direct to an opening formed in an artery, the formation having a heel and a toe at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter.

WO-A-9731591 discloses a flanged graft for end-to-side anastomosis grafting having an integral terminal flanged skirt or cuff, which facilitates an end-to-side anastomosis directly between an artery and the expanded flange bypass graft without need for an intervening venous collar or venous patch.

It has been proposed to provide a vascular prosthesis comprising a tube of synthetic material having an end formation for surgical connection directly to an opening formed in an artery, the end formation comprising an enlarged chamber serving to promote localised movement of blood having a non-laminar nature with a shear stress inducing relationship to the

arterial wall. The enlarged chamber has a convex outer wall. Further experimentation has revealed that this type of vascular prosthesis, whilst representing an improvement on the Miller cuff is still not ideal.

An object of this invention is to provide an improved vascular prosthesis for use in vascular surgery.

According to the present invention there is provided a vascular prosthesis comprising a tube of material other than autologous vascular tissue, said tube having an end formation for surgical connection direct to an opening formed in an artery, said formation comprising an enlarged chamber having a heel and a toe at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter, characterised in that transition between the tube and the toe is outwardly initially convex before a final concave portion (64), whereby said enlarged chamber serves to promote localised movement of blood having a non-laminar nature with shear stress inducing relationship to receiving arterial wall.

The heel of the enlarged chamber is formed at one end of the longer diameter, and the transition between the tube and the heel is preferably generally concave.

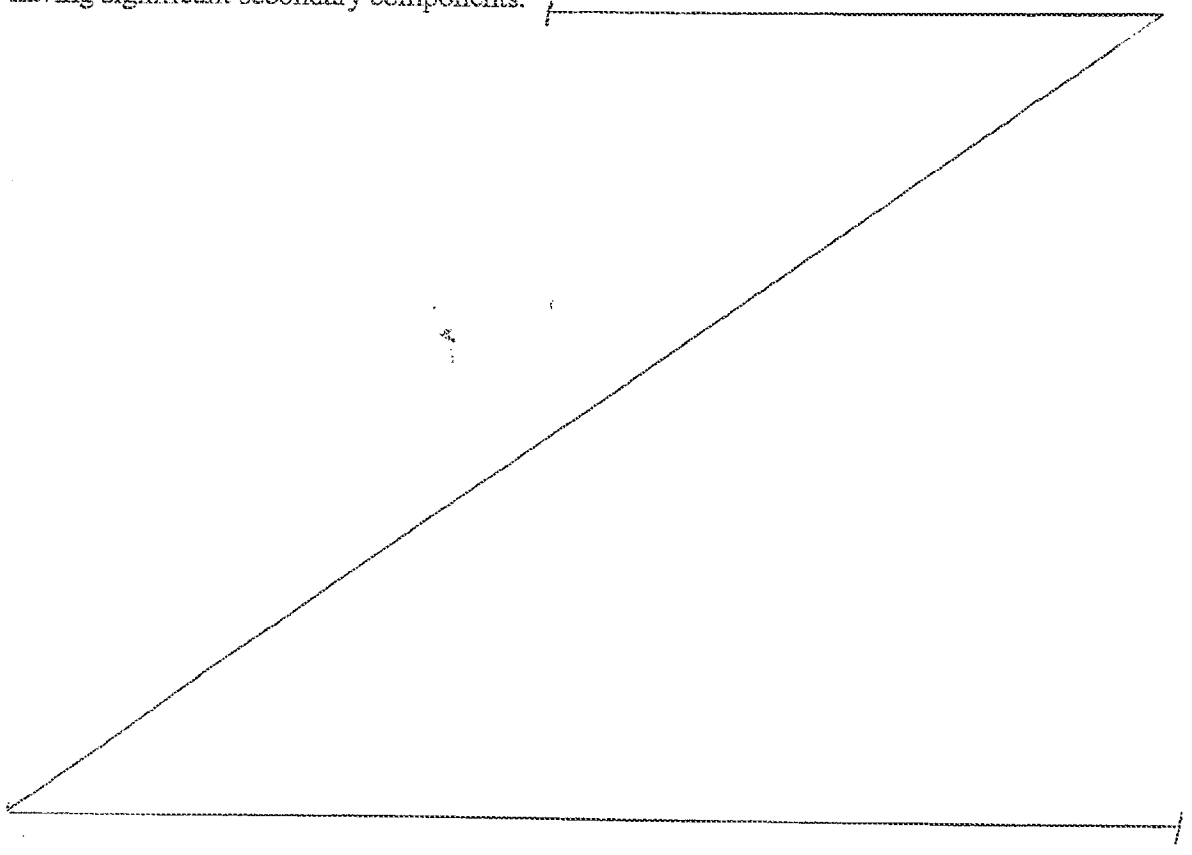
Transition between the tube and opposite ends of the shorter diameter is preferably outwardly convex.

It is also preferable that the tube have a narrower portion prior to transition to the enlarged chamber. It is believed that such narrowing of the tube will increase blood velocity entering the enlarged chamber of the prosthesis and hence increase shear stress in that region.

The vascular prosthesis of the invention is intended to promote vertical blood flow in the region of its arterial connection in order to reduce or eliminate regions of low shear stress and regions of long residence times where blood elements can accumulate in the region of the graft connection.

The grafts of the invention are preferably made of plastics material, especially polytetrafluoroethylene (PTFE).

The term "non-laminar" as used herein is intended to define blood flow other than parallel to arterial walls and, in particular, includes localised laminar movement of blood having significant secondary components.



Separation of flowing blood from the inner wall of the tube near its enlarged chamber, and associated with non-laminar flow, is preferably such as to produce a swirling action that may include locally circulatory or re-circulatory movement of blood, further preferably in the nature of or including a vortex action. Such blood flow separation will usually be at and adjacent preferred acute angling of the prosthesis tube for its direct connection to the artery, say at least partially within the enlarged chamber.

A preferred end chamber of the prosthesis tube of the invention is an enlargement which produces blood flow characteristics therein that result in an increase in wall shear stress.

Desired non-laminar blood flow promotion is preferably effective only in phases of cycles of blood-flow pulsing, which phases preferably alternate with other phases of more laminar flow sufficient to assist flow of all blood into the artery away and from that end of the prosthesis. The pulsed nature of normal blood flow involved successive time-spaced rises in pressure. Each pressure rise preferably causes both an initial relatively smooth or laminar blood flow in and out of the prosthesis-to-artery connection and a later transition into desired non-laminar blood movement. The preferred non-laminer vortex type movement preferably collapses before the next pressure rise.

This invention will now be further described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is an idealised sectional line diagram useful for explaining problems arising from simple direct connection or anastomoses of a prosthetic graft tube 10 of

synthetic material to an opening made in an artery 12;

Figure 2 shows use of a veinous cuff 34 interposed between a prosthetic graft tube 30 and an artery 32;

Figure 3 is a section through the graft of Figure 2 showing typical blood flow therethrough;

Figure 4 is a side view of a first prosthetic graft of the invention;

Figure 5 is a rear view of the graft of Figure 4;

Figure 6 is a view from below of the graft of Figure 4;

Figure 7 is a perspective view of the graft of Figure 4;

Figure 8 shows the graft of Figures 4 to 7 connected to an artery;

Figure 9 is a side view of a second prosthetic graft of the invention;

Figure 10 is a rear view of the graft of Figure 9;

Figure 11 is a view from below of the graft of Figure 9;

Figure 12 is a perspective view of the graft of Figure 9; and

Figure 13 shows the graft of Figures 9 to 12.

In the drawings, referring first to Figure 1, artery 12 has an opening made by an incision at 16. Prosthetic graft tube 10 of synthetic material (for which PTFE, most usually ePTFE, is widely used in practice) is run at an acute angle or more or less parallel to the artery 12. Tube 10 is indicated cut to an angled end 18 that is end to edge sewn into the opening 16. Unfortunately, there is a tendency for myointimal-hyperplasia to occur later in the receiving artery 12, see indicated development of fibrous or scare-like tissue in the toe and heel positions 11 and 13, respectively, and also at plate position 15 opposite the opening 16. This development can seriously

reduce the very blood flow that it is the object of the procedure to improve. Indeed, this condition all to often progresses to blocking of such blood flow altogether. These problems are all the greater the smaller the calibre of the receiving artery 12, which can be as small as 1 to 5mm for the type of distal by-passes often needed, say to go from the groin to beyond the knee as is frequently necessary to save a patient's lower leg.

Figures 2 and 3 of the drawings illustrate the Miller cuff, aimed at reducing such problems takes a short length of other vein, usually from still usable parts of the saphenous vein that would be used in its entirety if serviceable. This short length of autologous vein, typically 2 to 3mm in diameter, is removed and opened along its length, then sutured first to an opening 36 of the artery 32 and end-to-end to itself, see 39. The completed cuff 34 is trimmed and anastomoses completed, at 38 to normally wider prosthetic graft tube 30. The graft tube 20 is typically of PTFE and at least 4mm, preferably 6mm if not more, in diameter. Improvement in terms of reducing development of intimal hyperplasia was originally, and has since consistently been, attributed to the autologous vein-to-artery junction. The suppleness of the veinous tissue may also have contributed to this improvement by assisting absorption of pressure pulsing and reducing shear wall stress in the receiving artery. Wall shear stress was assumed and reported as being the major causative factor in development of intimal hyperplasia. This procedure has become popular and has been the subject of considerable development, including to use in a compared manner relative to interconnected small arteries.

Typical blood flow through the Miller cuff as shown in Figure 3. A vortex 40

is formed to increase shear stress but at opposite sides of the cuff low shear stress regions 42, 44 occur where accumulation of deposits can occur resulting in intimal hyperplasia. Furthermore where flow separates at the arterial wall opposite the cuff, a low shear stress region 46 also occurs where intimal hyperplasia is possible.

Turning to Figures 4 to 8 of the accompanying drawings a first vascular prosthetic graft 50 according to the invention is ideally made of polytetrafluoroethylene. The graft has a tubular part 52 of any desired length according to the length of the by-pass to be made using the graft and an enlargement 54 at one or both ends of the tube 52 (only one is shown). The enlargement 54 has an open end of a generally oval cross-section forming a heel 56 and a toe 58 at opposite ends of the larger diameter of the open end.

There is a generally outwardly concave transition 60 between the tube 52 and the heel 56 and between the tube 52 and the toe 58 a firstly convex (62) and a final concave (64) transition.

Sides 66 of the enlargement at opposite ends of the shorter diameter of the open end are generally outwardly convex.

The plane of the open end of the enlargement and of the tube 52 are generally parallel but it should be noted that prosthetic grafts having different separations thereof may be made for use in different situations. It should be further noted that prosthetic grafts having open ends of varying longer diameters may be produced. Furthermore, the degree of curvature either to the heel or the toe may be varied from graft to graft, in order to alter blood flow characteristics through the graft connection.

The prosthetic graft 50 is in practice connected to an artery by forming a slit

a side of an artery 67, opening out the slit and stitching the open end of the graft to the sides of the slit. It is to be noted that such connection of the graft causes the artery to have a concave underside opposite the graft as can be seen at 68 in Figure 8 of the drawings.

The length of the open end of the graft will probably be in the order of 14 to 36mm and the width of the open end is unlikely to be less than 6mm and probably not greater than 14mm.

Figures 9 to 13 illustrate a variation on the prosthetic graft of the persons embodiment. Like parts have been numbered similarly and only the main difference between them will now be described. In order to increase the velocity of blood flow through the graft connection to an artery, the tube 52 of the graft includes a narrower portion 70 prior to commencement of the enlargement.

CLAIMS

1. A vascular prosthesis (50) comprising a tube (52) of material other than autologous vascular tissue, said tube having an end formation for surgical connection direct to an opening formed in an artery, said formation comprising an enlarged chamber (54) having a heel (56) and a toe (58) at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter, characterised in that transition between the tube and the toe is outwardly initially convex (62) before a final concave portion (64), whereby said enlarged chamber serves to promote localised movement of blood having a non-laminar nature with a shear stress inducing relationship to receiving arterial wall.

2. A vascular prosthesis as claimed in claim 1, characterised in that transition (60) between the tube (52) and the heel (56) is generally outwardly concave.

3. A vascular prosthesis as claimed in claim 1 or 2, characterised in that transition between the tube (52) and opposite ends (66) of the shorter diameter is outwardly convex.

4. A vascular prosthesis as claimed in claim 1, 2 or 3 characterised in that the tube (52) has a narrower portion (70) prior to transition to the enlarged chamber.

5. A vascular prosthesis as claimed in any one of claims 1 to 4 characterised in that it is made of plastics material.

6. A vascular prosthesis as claimed in claim 5, characterised in that the plastics material is polytetrafluoroethylene.

ABSTRACT (Figure 8)

A vascular prosthesis (50) comprises a tube (52) of material other than autologous vascular tissue, the tube having an end formation for surgical connection direct to an opening formed in an artery, the formation comprising an enlarged chamber (54) having a heel (56) and a toe (58) at opposite ends of a first longer diameter parallel to the axis of the tube and a second shorter transverse diameter the enlarged chamber serving to promote localised movement of blood having a non-laminar nature with a shear stress inducing relationship to receiving arterial wall.

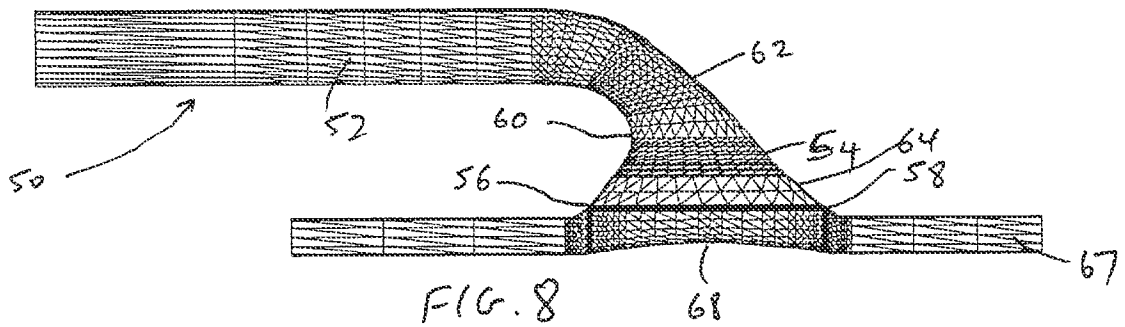


FIG. 8

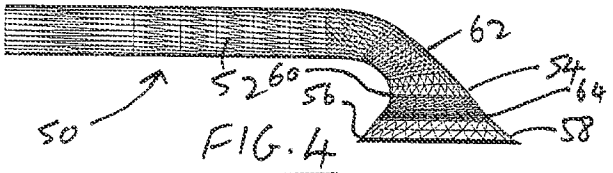


FIG. 4

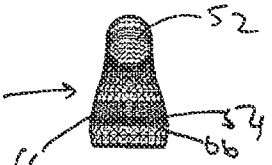


FIG. 5.

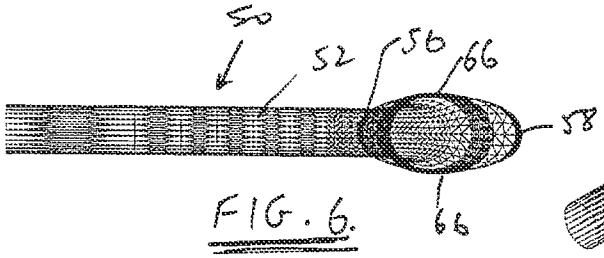


FIG. 6.

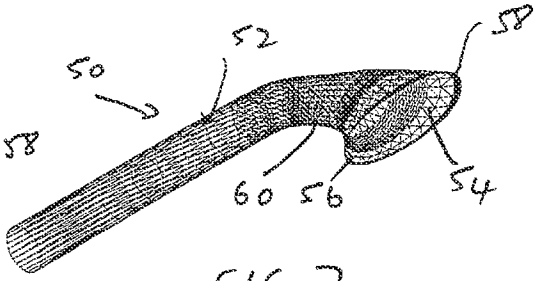


FIG. 7.

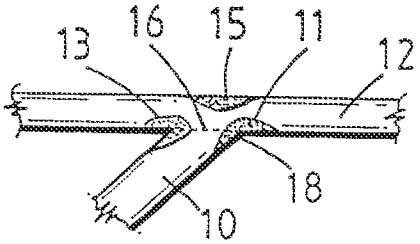


FIG. 1

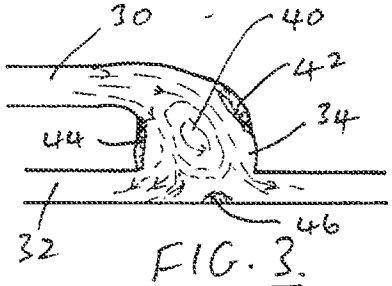


FIG. 3.

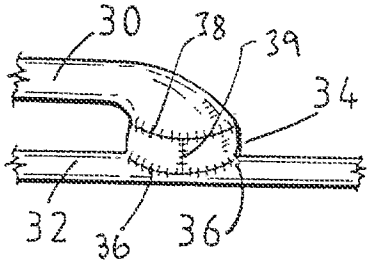


FIG. 2

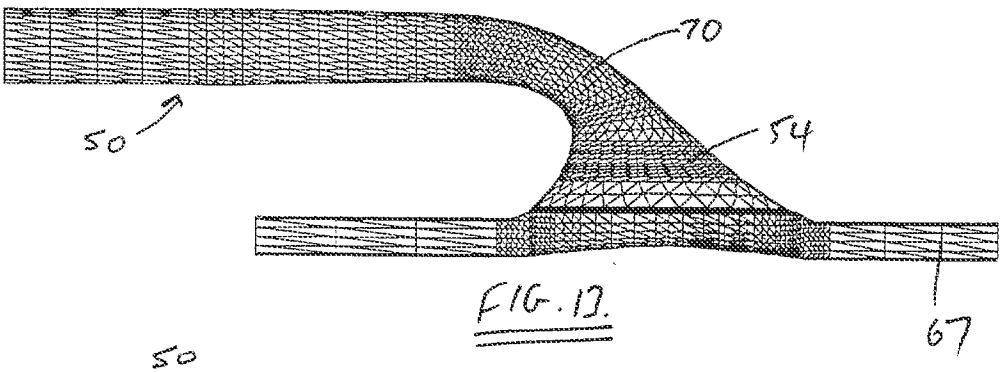


FIG. 13.

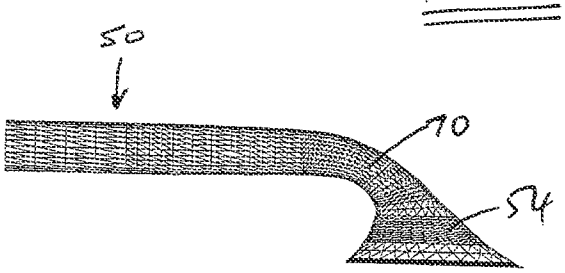


FIG. 9.

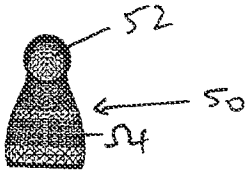


FIG. 10

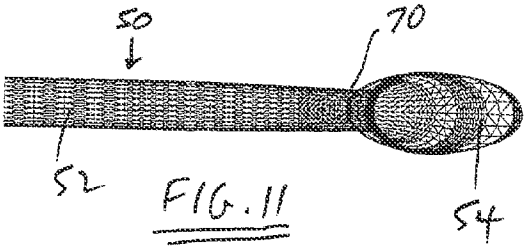


FIG. 11

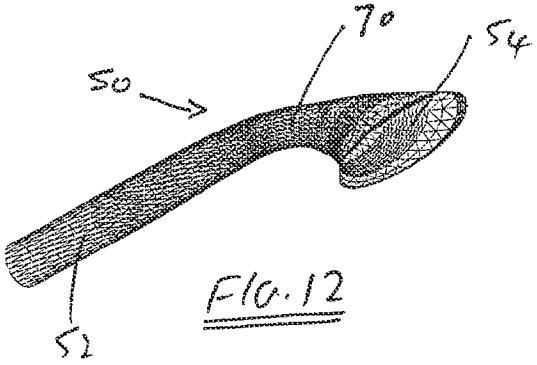


FIG. 12

PATENT
Docket No. 29791200162O
U.S. Serial No. 09/762,761

DECLARATION FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, WE HEREBY DECLARE THAT:

Our residence, post office address, and citizenship are as stated below next to our names.

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled: VASCULAR PROSTHESIS, the specification of which is attached hereto unless the following box is checked:

☒ Was filed on May 15, 1998 as PCT International Application No. PCT/GB98/01418.

WE HEREBY STATE THAT WE HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

We acknowledge the duty to disclose information which is material to the patentability as defined in 37 C.F.R. § 1.56.

We hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Application No.	Country	Date of Filing (day/month/year)	Priority Claimed?
9709967.5	GB	17/05/1997	☒Yes ☐No

We hereby claim benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date
*	

We hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, we acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial No.	Filing Date	Status
		☐Patented ☐Pending ☐Abandoned

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

25/7/01
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